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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,188	06/12/2001	Robert Shartle	LFS-115	4059

24353 7590 12/30/2003

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EXAMINER

ALEXANDER, LYLE

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,188

Applicant(s)

SHARTLE ET AL.

Examiner

Lyle A Alexander

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 33-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 33-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20,33-39 and 49-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,501,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device for determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level.

Claims 1-20 and 33-53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/879,146. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device and method for the determination of blood glucose comprising means to draw blood, a

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porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8,20 and 33-53 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-57 of copending Application No. 09/878,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to a device and method of use for the determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 09/878,742 in view of Joseph.

Copending Application No. 09/878,742 teaches to a device for determination of blood glucose comprising means to draw blood, a porous electrode, a gel matrix and means to correlated the measured value to a blood glucose level. Copending Application No. 09/878,742 is silent to the claimed porous electrode.

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Joseph teaches in column 3 that it is known to use porous electrodes in devices that determine glucose in body fluids. Porous electrodes have the advantage of permitting passage of interstitial fluid, which facilitates real time analysis.

It would have been within the skill of the art to modify copending Application No. 09/878,742 in view of Joseph and use a porous electrode to gain the above advantages.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5-8,20 and 33-54 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gough.

Gough teach an electrochemical cell for the determination of glucose in blood comprising a housing(10), a fine hollow needle suitable for piercing the skin, oxygen sensors(18 and 16) and an oxidase enzyme embedded in a porous gel(20) that surrounds the sensors. Column 3 lines 1-5 teach the gel matrix can be an acrylamide or acrylic polymer. A reference electrode(28) is also taught. Column 4 lines 3-20 teach the amount of glucose is proportional to the output of the two sensors. Figure 1 teaches that adjustments in current have a differential effect on the measuring device.

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The claimed skin-piercing member has been read on the taught fine hollow needle suitable for piercing the skin. The claimed electrochemical cell has been read on the sensors(16 and 18). The claimed constituent transfer medium has been read on the taught acrylamide or acrylic polymers. The claimed means for sending an electrical signal and software algorithm have been read on the taught sensor output. The claimed control means have been read on the taught reference electrode(28). The claimed hand held configuration has been read on the teaching the device(10) is held up to the skin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Nitzan.

See Gough *supra*.

Gough is silent to the claimed natural gel matrix of agarose or starch.

Nitzan teach an electrochemical glucose sensor. Column 6 lines 49-53 teach "many types of polymers are suitable ones such as for examples polyacrylamide , polyacrylic acid agarose starch...". The Office has read this passage as teach the equivalence of polyacrylamide , polyacrylic acid, agarose and starch.

It would have been within the skill of the art to modify Gough in view of Nitzan and use other equivalent gel materials such as agarose or starch as experimental design choice.

Claims 9-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough in view of Joseph.

See Gough supra.

Gough is silent to the claimed porous electrode.

Joseph teaches in column 3 that it is known to use porous electrodes in devices that determine glucose in body fluids. Porous electrodes have the advantage of permitting passage of interstitial fluid, which facilitates real time analysis.

It would have been within the skill of the art to modify Gough in view of Joseph and use a porous electrode to gain the above advantages.

Gough is silent to the claimed porosity/pore size and distance between the electrodes.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known results. The choice of porosity of the electrodes as well as the spacing of the electrodes would have been result effective variables. It would have been within the skill of the art to modify Gough in view of Joseph and select the porosity of the electrodes as being 100-150 microns and the electrode spacing of 100-500 angstroms as optimization of result effective variables.

Response to Arguments

Applicant's arguments filed 10/7/03 have been fully considered but they are not persuasive.

Applicants traverse the ODP rejection over 6,501,976 on the basis the patent is directed to concentrically spaced electrodes whereas the instant claims do not contain the specific limitations of the patent. The Office maintains the instant claims are broader than the patent claims and properly read on them as none of the structures in the patent are excluded by the instant claims.

Applicants traverse the provisional obviousness-type double patenting rejections over 09/878,742 on the basis that claims being allowable in this application are directed to claims not obvious with the instant claims. In the absence of presenting the allowed claims, the Office will maintain the rejection over the claims of the PGPUB 2002/0188221. However, upon allowance of 09/878,742, the rejection will be reconsidered.

Applicants traverse Gough on the grounds they fail to teach a planar electrode. In the absence of better defining what is intended by a planar electrode as an electrode located within a plane and having two dimensional characteristics. The Office maintains Gough teaches electrode (34) that meets the meaning of planar.

Applicants traverse the remainder of the claims on the basis the rejection over Gough is improper. The Office as stated above believes the rejections of record have been properly read on the instant claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
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